CERN against COVID-19

Task Force

SAFETY AND PERFORMANCE REPORT

Face shield project

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Distribution to
# Modifications

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<td>All</td>
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1 INTRODUCTION

This document describes the face protection shields produced by CERN in the framework of risk mitigation devices adopted during the COVID-19 crisis.

2 PURPOSE AND SCOPE

The European Commission issued an official recommendation to the member states on the conformity assessment and market surveillance procedures during the COVID-19 crisis, which provides guidance to national bodies on allowing non-CE-marked PPE (Personal Protection equipment). However, the PPE still needs to be in compliance with the applicable essential health and safety requirements.

The extent to which compliance such requirements is achieved with this PPE, including conformity tests, is described below. The design and manufacturing are based on the applicable European standards (EN), i.e. EN 166:2002 - a harmonized standard under the EU Regulation 2016/425, which is also recognised in Switzerland.

3 FACE SHIELDS

These face shields are for use exclusively as PPE against splashes, sprays and spatter of body fluids in the specific context of COVID-19. Since this PPE does not protect against aerosol inhalation, we recommend to use the face shield not alone, but in conjunction with other protective equipment, e.g. a mask.

3.1 FACE SHIELD DESIGN

The face shield is designed to have the visor at about 5 cm distance from the face. This allows the use of glasses.

3.2 LIST OF COMPONENTS – MATERIALS

The face shield consists of:

- the visor made of a 0.25 mm thick PET foil.
- The support made of injection moulded PP (authorized for food). The buckle made of injection moulded PP (authorized for food).
- The elastic tape to fix the system around the head.

Drawings of the main components (support and visor)
# 4 Safety and Performance Requirements

The table below indicates the essential health and safety requirements according to EN 166:2002 and the verifications carried out for the CERN face shields object of this document.

<table>
<thead>
<tr>
<th>Main Requirement</th>
<th>ID</th>
<th>Sub-requirement</th>
<th>Observations</th>
<th>Verified (Y/N)</th>
<th>Ref</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>General</strong></td>
<td>G1</td>
<td>Construction</td>
<td>Shall be free from projections, sharp edges or other defects which are likely to cause discomfort or injury during use.</td>
<td>Y</td>
<td>§3</td>
</tr>
<tr>
<td></td>
<td>G2</td>
<td>Materials</td>
<td>No parts of the eye-protector which are in contact with the wearer shall be made of materials which are known to cause any skin irritation.</td>
<td>Y</td>
<td>§3</td>
</tr>
<tr>
<td></td>
<td>G3</td>
<td>Headband</td>
<td>Shall be at least 10 mm wide over any portion which may come into contact with the wearer’s head. Headbands shall be adjustable or self-adjusting.</td>
<td>Y</td>
<td>§3</td>
</tr>
<tr>
<td></td>
<td>G4</td>
<td>Field of Vision</td>
<td>Shall pass the according to §17 of EN 168:2002.</td>
<td>Y</td>
<td>§3</td>
</tr>
<tr>
<td></td>
<td>G5</td>
<td>Transmittance</td>
<td>Shall have a luminous transmittance greater than 74.4 %.</td>
<td>Y</td>
<td>§3</td>
</tr>
<tr>
<td><strong>Robustness</strong></td>
<td>R1</td>
<td>Minimum robustness</td>
<td>Withstands the application of a 22 mm nominal diameter steel ball with a force of (100 ± 2) N.</td>
<td>N</td>
<td>§5</td>
</tr>
<tr>
<td><strong>Fire</strong></td>
<td>F1</td>
<td>Ignition</td>
<td>No part of the eye-protector ignites or continues to glow after removal of the heat source.</td>
<td>N</td>
<td>§5</td>
</tr>
<tr>
<td>Protection against droplets and splashes of liquids</td>
<td>D1</td>
<td>Pass tests</td>
<td>No pink or crimson colouration appears in the ocular regions defined by the two circles when assessing goggles for protection against droplets. No account shall be taken of any such colouration up to a distance of 6 mm inside the edges of the eye-protector.</td>
<td>Y</td>
<td>§3</td>
</tr>
<tr>
<td>---------------------------------------------------</td>
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<td>-----------------------------</td>
<td>-----------------------------------------------------------------------------------------------------------------</td>
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<td>------</td>
</tr>
<tr>
<td>D2</td>
<td>Viewing area</td>
<td>Shall have a viewing area with a minimum vertical centre-line depth of 150 mm when mounted in the appropriate housing.</td>
<td>Y</td>
<td>§3</td>
<td></td>
</tr>
<tr>
<td>Fogging</td>
<td>FO1</td>
<td>Fogging resistance</td>
<td>Shall remain free from fogging.</td>
<td>Y</td>
<td>§3</td>
</tr>
<tr>
<td>Labelling / Marking</td>
<td>M1</td>
<td>Marking on the frame</td>
<td>‘Protection against droplets and liquids only’, ‘R8.01-3’, ‘COVID 19’</td>
<td>Y</td>
<td>§3</td>
</tr>
</tbody>
</table>
5 **CONFORMITY TESTS**

Where required by EN 166:2002 conformity was tested according to EN 168:2002.

### 5.1 RESULTS

<table>
<thead>
<tr>
<th>Test</th>
<th>Requirement</th>
<th>Result (Pass / Fail)</th>
<th>Observations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Verification</td>
<td>Visual inspection</td>
<td>Pass</td>
<td>No sharp edges in contact with skin; easily adjustable headband.</td>
</tr>
<tr>
<td>Robustness</td>
<td>Test according to clause 4 of EN 168:2002</td>
<td>Not done</td>
<td>The intent of this mask is to protect against droplets and splashes of liquid from infected COVID-19 patients.</td>
</tr>
<tr>
<td>Fire</td>
<td>Test according to clause 4 of EN 168:2002</td>
<td>Fail</td>
<td>Shall not be in contact with any heat source greater than 150°C.</td>
</tr>
<tr>
<td>Performance</td>
<td>Test according to clauses 10.2 and 12.2 of EN 168:2002</td>
<td>Pass</td>
<td></td>
</tr>
</tbody>
</table>

6 **DISCLAIMER BEFORE USE**

The fire resistance and minimum robustness requirements of EN 168:2002, are not met.

It should also be noted that CERN has not yet obtained any approvals or certifications from the competent Host State authorities, in so far as such approvals or certifications are required.

Notwithstanding the foregoing, in light of the present COVID-19 emergency situation, CERN has accepted urgent requests from neighbouring authorities and institutions to receive Face Shields for COVID-19-related purposes.

By accepting face shields from CERN, the recipient is deemed to have read and understood this Safety and Performance Report. The recipient accepts liability for their
use and agrees to hold CERN free and harmless from all liability arising through or in connection with the possession and use of the face shields.

7 Use

ONLY use this face shield as PPE against splashes, sprays and spatter of body fluids in the specific context of COVID-19.

PROTECT the face shield from any source of heat.

DO NOT use this shield as protection against any impact.

This PPE is intended for personal use and should not be shared between different users. In case shared use of the face-shield cannot be avoided, the face-shield must properly disinfected prior to its handover to another user.

In all cases, the face shields must be used in accordance with applicable regulations and best practices regarding the use of PPE. COVID-19 related hygienic measures must also be followed.